

August 10, 2001

VETERINARY SERVICES MEMORANDUM NO. 800.93

Subject: Supplemental Assay Methods

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team

I. PURPOSE

The purpose of this memorandum is to present a current list of Supplemental Assay Methods (SAMs) which describe procedures, methods, and techniques used by the Center for Veterinary Biologics-Laboratory (CVB-L) for official assays of biological products according to 9 CFR 113.2(a).

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 700.4 dated July 8, 1999, and the Listing of Supplemental Assay Methods dated July 1999.

III. APPLICATION

A. SAMs contain detailed instructions for conducting officially required tests. They do not supersede the requirements in the 9 CFR or those in filed Outlines of Production specifically requiring alternative procedures for the licensee or CVB-L.

B. CVB-L must follow SAMs. Revised SAMs must be issued before implementation by CVB.

IV. IDENTIFICATION OF SAMs

A. CVB-L will utilize a standardized title page format on all SAMs which includes the testing protocol heading, the descriptive title of the document, the date of the most recent version, the number, the standard requirement to which it applies, and the name of a person who has agreed to act as primary contact for comments and questions about the document.

B. Reference to these Supplemental Assay Methods should be made by the letters "SAM" and the applicable number.

C. CVB will number revisions of SAMs the same as the original and show the new date of issuance with the date of the one being superseded.

V. PREPARATION AND DISTRIBUTION

CVB will prepare and distribute SAMs. Initial distribution will be made electronically or by hardcopy to licensees, permittees, applicants, and appropriate Veterinary Services personnel. You may obtain additional copies by accessing the CVB home page at <http://www.aphis.usda.gov/vs/cvb>, or by sending a request to the CVB-L, 1800 Dayton Avenue, P.O. Box 844, Ames, Iowa 50010.

VI. AVAILABILITY

CVB will periodically issue notices of the addition, revision, or deletion of SAMs. CVB will maintain a current listing of SAMs on the CVB home page.

/s/ Chester A. Gipson for

Alfonso Torres
Deputy Administrator
Veterinary Services

Enclosure

LISTING OF SUPPLEMENTAL ASSAY METHODS

August 2001

100 Series

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|-----|---|-------------------|
| 101 | Supplemental Assay Method for Titration of Bovine Virus Diarrhea Virus in Vaccines | September 1, 1981 |
| 102 | Supplemental Assay Method for Titration of Parainfluenza-3 Virus in Vaccines | January 1982 |
| 104 | Supplemental Assay Method for Isolation of Parainfluenza-3 Virus from Nasal Secretions | July 29, 1983 |
| 105 | Supplemental Assay Method for Titration of Infectious Bovine Rhinotracheitis Virus in Vaccines | January 26, 2001 |
| 107 | Supplemental Assay Method for Titration of Neutralizing Antibody (Constant Serum - Varying Virus Method) | June 14, 1971 |
| 108 | Supplemental Assay Method for the Detection of Extraneous Bovine Viral Diarrhea Virus in Modified-Live Vaccines | March 1, 2001 |
| 109 | Supplemental Assay Method for Titration of Infectious Bovine Rhinotracheitis Neutralizing Antibody by a Virus Plaque Method | April 10, 1985 |

- 110 Supplemental Assay Method for Titration of Serum for Eastern and Western Equine Encephalomyelitis Antibody Content by the Plaque Reduction Neutralization Method
February 17, 1998
- 111 Supplemental Assay Method for Titration of Infectious Bovine Rhinotracheitis Virus Neutralizing Antibody (Constant Virus - Varying Serum Method)
August 19, 1983
- 112 Supplemental Assay Method for Titration of Bovine Virus Diarrhea Neutralizing Antibody (Constant Virus - Varying Serum Method)
1984
- 113 Supplemental Assay Method for Titration of Parainfluenza-3 Neutralizing Antibody (Constant Virus - Varying Serum Method)
August 19, 1983
- 114 Supplemental Assay Method for Titration of Porcine Transmissible Gastroenteritis Virus
November 16, 1998 (DRAFT)
- 115 Supplemental Assay Method for Titration of Bovine Virus Diarrhea Neutralizing Antibody (Constant Serum - Varying Virus Method)
June 1985
- 116 Supplemental Assay Method for Phenotypic Examination of Pseudorabies Virus for Thymidine Kinase Activity by a Plaque Selection Method
November 20, 2000
- 117 Supplemental Assay Method for Titration of Pseudorabies Virus Neutralizing Antibody (Constant Virus - Varying Serum Method)
August 3, 1998
- 118 Supplemental Assay Method for Titration of Pseudorabies Virus in Vaccines
October 29, 1998

- 120 Supplemental Assay Method for the *In Vitro* Potency Assay of Bovine Respiratory Viruses in Killed Vaccines
November 1, 1991 (DRAFT)
- 121 Supplemental Assay Method for Titration of Porcine Rotavirus in Modified-live Vaccines
September 25, 2000 (DRAFT)
- 122 Supplemental Assay Method for Titration of Porcine Rotavirus Antibody (Constant Virus - Varying Serum Method)
March 6, 2001 (DRAFT)
- 123 Supplemental Assay Method for Pseudorabies Virus Challenge Test in Swine
March 2, 1999
- 124 Supplemental Assay Method for Conducting the Hemagglutination Inhibition Assay for Equine Influenza Antibody
March 8, 2001 (DRAFT)
- 125 Supplemental Assay Method for Titration of Bovine Rotavirus in Vaccines
September 1, 1995 (DRAFT)
- 126 Supplemental Assay Method for Titration of Bovine Rotavirus Antibody
September 1, 1995 (DRAFT)

200 Series

- 200 Supplemental Assay Method for Potency Testing Products Containing *Clostridium chauvoei* Antigen
April 15, 1998
- 201 Supplemental Assay Method for Potency Testing *Clostridium perfringens* Type C Beta Antigen
April 26, 1999

- 20 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
Type C Antitoxins
October 29, 1998
- 203 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
Type D Epsilon Antigen
June 19, 2000
- 204 Supplemental Assay Method for Potency Testing *Clostridium perfringens*
Type D Antitoxins
January 23, 1999
- 206 Supplemental Assay Method for Potency Testing of Tetanus Antitoxin
May 1, 1987
- 207 Supplemental Assay Method for Potency Testing *Clostridium novyi* Type
B Antigen
November 5, 1999
- 209 Supplemental Assay Method for Potency Testing Products Containing
Clostridium haemolyticum Antigen
February 16, 1999
- 212 Supplemental Assay Method for Potency Testing *Clostridium sordellii*
Antigen
August 25, 1998
- 213 Supplemental Assay Method for Potency Testing of *Clostridium*
botulinum Type C Bacterin-Toxoids
September 23, 1980
- 214 Supplemental Assay Method for Immunogenicity and Spore Count Testing
of Anthrax Spore Vaccine-Nonencapsulated
February 16, 1999

- 216 Supplemental Assay Method for Potency Testing of Commercial Equine
Tetanus Antitoxin by CELISA
May 28, 1999

- 217 Supplemental Assay Method for Potency Testing of Tetanus Toxoid by
ELISA November 5, 1999

300 Series

- Supplemental Assay Method for Titration of Canine Distemper Virus in
Primary Cell Culture
November 12, 1999

- 303 Supplemental Assay Method for the Titration of Distemper Virus in
Embryonated Chicken Eggs
August 24, 2000

- 304 Supplemental Assay Method for Titration of Infectious Canine Hepatitis
Virus in Primary Canine Kidney Cell Culture
August 23, 2000

- 305 Supplemental Assay Method for the Titration of Feline Panleukopenia
Virus in Cell Culture
July 1, 1999

- Supplemental Assay Method for the Titration of Feline Calicivirus in Cell Culture
- March 6, 2001

- 307 Supplemental Assay Method for the Titration of Feline Rhinotracheitis
Virus in Cell Culture
March 5, 2001

- 308 Supplemental Assay Method for Potency Testing of Inactivated Rabies
Vaccine in Mice Using the National Institutes of Health Test
October 7, 1999
- 309 Supplemental Assay Method for the Titration of Canine Parainfluenza
Virus
June 1, 1985
- 310 Supplemental Assay Method for Scoring Feline Calicivirus in Cats
Following Challenge
March 5, 1999
- 311 Supplemental Assay Method for Scoring Feline Rhinotracheitis Virus in
Cats Following Challenge
March 5, 1999
- 312 Supplemental Assay Method for the Detection of Extraneous
Cytopathogenic Agents in Master Seed Virus
July 16, 1999
- 313 Supplemental Assay Method for the Detection of Extraneous
Hemadsorbing Agents in Master Seed Virus
December 22, 1999
- 314 Supplemental Assay Method for Detection of Extraneous Viruses by the
Fluorescent Antibody Test
June 1, 1985
- 315 Supplemental Assay Method for the Detection of Serum Neutralizing
Antibodies to Rabies Virus Using the Rapid Fluorescent Focus Inhibition
Test (RFFIT)
March 1, 1986
- 316 Supplemental Assay Method for the Titration of Canine Parvovirus in
Cell Culture
December 22, 1999

- 317 Supplemental Assay Method for Titration of Canine Adenovirus in
Canine Kidney Cell Culture
December 22, 1999
- 318 Supplemental Assay Method for Evaluation by the Relative Potency
Method of *In Vitro* Enzyme Immunoassays Used in Testing of Veterinary
Vaccines
July 9, 2001
- 319 Supplemental Assay Method for Titration of Feline *Chlamydia psittaci* in
Cell Culture
March 5, 2001
- 320 Supplemental Assay Method for Titration of Feline *Chlamydia psittaci* in
Embryonated Chicken Eggs
March 5, 2001
- 321 Supplemental Assay Method for Quantitating the gp70 Antigen of Feline
Leukemia Virus Veterinary Vaccines
December 22, 1999 (DRAFT)
- 322 Supplemental Assay Method for Determination of the Specific Viral
Antigen Content in Inactivated Canine Coronavirus Vaccines
March 22, 1999 (DRAFT)
- 323 Supplemental Assay Method for Titration of Canine Distemper Virus in
Vero Cell Culture
November 12, 1999

400 Series

- 405 Supplemental Assay Method for Detecting Lymphoid Leukosis
Biocontamination by the COFAL Test
June 21, 2000

- 406 Supplemental Assay Method for Titration of Herpesvirus of Turkeys
(Strain FC-126) or Chicken Herpesvirus (Strain SB-1)
October 29, 1998
- 407 Supplemental Assay Method for Titration of Herpesvirus of Turkeys
(Strain FC-126), Lyophilized
October 29, 1998
- 408 Supplemental Assay Method for Titrating Tissue Culture Adapted
Vaccine Strains of Infectious Bursal Disease Virus
December 16, 1998
- 409 Supplemental Assay Method for Titrating the Fractions of Combination
Avian Encephalomyelitis/Pox Vaccine
December 16, 1998
- 411 Supplemental Assay Method for the Titration of Newcastle Disease
Vaccine, Infectious Bronchitis Vaccine, and Combination Newcastle
Disease-Infectious Bronchitis Vaccine in Chicken Embryos
October 29, 1998

500 Series

- 504 Supplemental Assay Method for the Manual Determination of Protein
Content of Veterinary Biologics (Biuret)
April 24, 1997
- 509 Supplemental Assay Method for the Mikrozone-Electrophoretic
Separation of Blood Fractions Used in Veterinary Biologics
April 24, 1997
- 510 Supplemental Assay Method for the Manual Determination of
Formaldehyde in Veterinary Biologics (Schiff Test)
May 5, 1997

513 Supplemental Assay Method for the Determination of Protein and Phenol in PPD (Purified Protein Derivative Produced From Cultures of *Mycobacterium bovis* Strain AN-5) Bovis Tuberculin
July 26, 2000

514 Supplemental Assay Method for the Determination of Hydrogen Ion Concentration, Total Nitrogen, TCA Nitrogen, Phenol and Clarity in Intradermic (Filtrate Produced From Cultures of Pn, C, and Dt Strains of *Mycobacterium tuberculosis*) Tuberculin
July 26, 2000

600 Series

600 Supplemental Assay Method for Purity, Potency and Dissociation of *Brucella abortus* Vaccine, Strain 19
June 19, 2000

601 Supplemental Assay Method for Potency Testing of Erysipelas Antiserum in Mice
March 19, 1999

602 Supplemental Assay Method for Evaluation of Salmonella Pullorum Antigens
April 11, 1986

603 Supplemental Assay Method for Potency Testing of Fowl Cholera (*Pasteurella multocida*) Bacterins, Type 3
March 18, 1999

604 Supplemental Assay Method for the Evaluation of Koch's Old Tuberculin
March 22, 1999

605 Supplemental Assay Method for Potency Testing of Erysipelas Bacterins in Swine
May 25, 1982

- 606 Supplemental Assay Method for Potency Testing of Erysipelas Vaccines
in Swine
May 20, 1982
- 607 Supplemental Assay Method for Potency Testing of Fowl Cholera
(*Pasteurella multocida*) Bacterins, Type I
March 17, 1999
- 608 Supplemental Assay Method for Potency Assay of *Leptospira*
interrogans Serovar *pomona* Bacterins
July 1, 1999
- 609 Supplemental Assay Method for Potency Assay of *Leptospira*
interrogans Serovar *canicola* Bacterins
July 1, 1999
- 610 Supplemental Assay Method for Potency Assay of *Leptospira*
interrogans Serovar *icterohaemorrhagiae* Bacterins
July 1, 1999
- 611 Supplemental Assay Method for Potency Testing of Erysipelas Bacterins
in Mice
December 20, 1999
- 612 Supplemental Assay Method for Bacterial Plate Count of *Erysipelothrix*
rhusiopathiae Vaccines
November 4, 1999
- 613 Supplemental Assay Method for Potency Testing of Erysipelothrix
Rhusiopathiae Bacterins
April 7, 1994 (DRAFT)
- 617 Supplemental Assay Method for Potency Assay of *Leptospira*
interrogans Serovar *grippotyphosa* Bacterins
July 1, 1999

- 620 Supplemental Assay Method for Potency Testing Enterotoxigenic (K99 Pilus) *Escherichia coli* Bacterins
April 28, 1999 (DRAFT)
- 621 Supplemental Assay Method for Potency Testing Enterotoxigenic (K88 Pilus) *Escherichia coli* Bacterins
April 28, 1999 (DRAFT)
- 622 Supplemental Assay Method for Potency Testing Enterotoxigenic (987P Pilus) *Escherichia coli* Bacterins
April 30, 1999 (DRAFT)
- 623 Supplemental Assay Method for Potency Testing Enterotoxigenic (F41 Pilus) *Escherichia coli* Bacterins
April 30, 1999 (DRAFT)
- 624 Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serovar *pomona* Bacterins
August 30, 2000
- 625 Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serovar *canicola* Bacterins
August 30, 2000
- 626 Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serovar *grippotyphosa* Bacterins
August 30, 2000
- 627 Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serovar *icterohaemorrhagiae* Bacterins
August 30, 2000
- 630 Supplemental Assay Method for Potency Testing of Fowl Cholera (*Pasteurella multocida*) Bacterins, Type 4
February 6, 1999

- 631 Currently not available; revision in progress
- 632 Supplemental Assay Method for Potency Testing of *Salmonella choleraesuis* Bacterins
December 15, 1999
- 633 Currently not available; revision in progress
- 634 Supplemental Assay Method for Potency Testing of *Pasteurella multocida* Bacterins of Bovine Origin
June 6, 2000
- 635 Supplemental Assay Method for Potency Testing of *Pasteurella multocida* Bacterins of Porcine Origin
June 6, 2000
- 636 Supplemental Assay Method for the Evaluation of Tuberculin Purified Protein Derivative (PPD)
May 22, 2000

800 Series

- 801 Supplemental Assay Method for Examination of Porcine Cells for Porcine Parvovirus Contamination
September 16, 1983
- 802 Supplemental Assay Method for Identification of Vaccine Strains of Newcastle Disease Virus
December 16, 1998
- 803 Supplemental Assay Method for Examination of Trypsin Solutions for Porcine Parvovirus Contamination
October 14, 1983

900 Series

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| 900 | Supplemental Assay Method for Testing Growth Promoting Qualities of Fluid Thioglycollate Medium and Soybean-Casein Digest Medium using <i>Bacillus subtilis</i> Spores and <i>Candida krusei</i> as the Indicator Organisms
March 22, 1999 |
| 901 | Supplemental Assay Method for Testing Growth-Promoting Qualities of Fluid Thioglycollate Medium with Beef Extract Using <i>Clostridium chauvoei</i> Spores as the Indicator Organism
March 3, 1999 |
| 902 | Supplemental Assay Method for Testing Growth Promoting Qualities of Brain Heart Infusion Agar Using <i>Bacillus Subtilis</i> Spores and <i>Candida Krusei</i> as Indicator Organisms
July 13, 1999 |
| 903 | Supplemental Assay Method for Testing for Preservative Interference with Sterility Tests
November 4, 1999 |
| 904 | Supplemental Assay Method to Test for Bactericidal Activity of Diluents Used with Live Bacterial Vaccines
November 5, 1999 |
| 905 | Supplemental Assay Method for Test for Potency of Live Avirulent <i>Pasteurella haemolytica</i> Vaccine
December 15, 1999 |
| 906 | Supplemental Assay Method for Sterility Testing of Preparations Other Than Live Vaccines
December 16, 1998 |
| 908 | Supplemental Assay Method for Sterility Testing of Live Viral Vaccines
April 21, 1999 |

- 909 Supplemental Assay Method for Sterility Testing of Live Viral Vaccines
of Chicken Embryo Origin Recommended for Nonparenteral Injection
December 21, 1999
- 910 Supplemental Assay Method for Detection of Mycoplasma
Contamination
November 9, 2000
- 918 Supplemental Assay Method for Bacterial Count of *Pasteurella*
multocida, Avian Isolates, Vaccines.
November 10, 1999
- 928 Supplemental Assay Method for Detection of Extraneous Bacteria and
Fungi in Live Bacterial Vaccines
November 9, 2000